

UNITED STATES PATENT AND TRADEMARK OFF

Re:

Application of:

Anand R. Baichwal, et al.

Serial No.:

09/676,376

Filed:

September 29, 2000

For:

SUSTAINED RELEASE MATRIX SYSTEMS FOR

HIGHLY SOLUBLE DRUGS

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

June 7, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.56 and 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (10 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application.

Pursuant to 37 C.F.R. § 1.98(a), copies of these references are hereby enclosed.

Applicants respectfully advise the Examiner that this IDS lists references cited in other patent filings of the Assignee concerning the Assignee's controlled release technology platform. The office of the undersigned has not undertaken a separate review of the cited references and the Examiner is invited to undertake his own review of these references to ascertain their applicability to the presently claimed invention.

Applicants also respectfully advise the Examiner of the following related U.S. Patents 06/11/2002 RHARISH applications which are commonly assigned:

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U.S. Patent No. 5,472,711, "Agglomerated Hydrophilic Complexes With Multi-



- Phasic Release Characteristics", issued on December 5, 1995;
- U.S. Patent No. 5,670,168, "Agglomerated Hydrophilic Complexes With Multi-Phasic Release Characteristics", issued on September 23, 1997;
- U.S. Patent No. 5,455,046, "Sustained Release Heterodisperse Hydrogel Systems For Insoluble Drugs", issued on October 3, 1995;
- U.S. Patent No. 5,512,297, "Sustained Release Heterodisperse Hydrogel Systems For Insoluble Drugs", issued On April 30,1996;
- U.S. Patent No. 5,554,387, "Sustained Release Heterodisperse Hydrogel Systems For Insoluble Drugs", issued on September 10, 1996;
- U.S. Patent No. 5,667,801, "Sustained Release Heterodisperse Hydrogel Systems For Insoluble Drugs", issued on September 16, 1997;
- U.S. Patent No. 5,846,563, "Sustained Release Heterodisperse Hydrolgel Systems For Insoluble Drugs", issued on December 8,1998;
- U.S. Patent No. 5,773,025, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued on June 30, 1998;
- U.S. Patent No. 6,048,548, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued on April 11, 2000;
- U.S. Patent No. 6,245,356, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued on June 12, 2001;
- U.S. Patent No. 6,136,343, "Sustained Release Heterodisperse Hydrogel Systems For Insoluble Drugs", issued on October 24, 2000;
- U.S. Patent No. 5,399,358, "Sustained Release Formulation For 24 Hour Release Metoprolol", issued on March 21, 1995;
- U.S. Patent No. 4,994,276, "Compressible Sustained Release Excipient", issued on February 19, 1991;
- U.S. Patent No. 5,128,143, "Sustained Release Excipient And Tablet Formulation", issued on July 7, 1992;
 - U.S. Patent No. 5,135,757, "Compressible Sustained Release Excipient", issued

- on August 4,1992;
- U.S. Patent No. 5,169,639, "Controlled Release Verapamil Tablet", issued on December 8, 1992;
- U.S. Patent No. 5,330,761, "Bioadhesive Tablet For Non-Systemic Use Products", issued on July 19, 1994;
- U.S. Patent No. 5,478,574, "Agglomerated Hydrophilic Complexes With Multi-Phasic Release Characteristics", issued on December 26, 1995;
- U.S. Patent No. 5,399,359, "Controlled Release Oxybutynin Formulations", issued on March 21, 1995;
- U.S. Patent No. 5,399,362, "Once-A-Day Metoprolol Oral Dosage Form", issued on March 21, 1995;
- U.S. Patent No. 5,612,053, "Controlled Release Insufflation Carrier For Medicaments", issued on March 18, 1997;
- U.S. Patent No. 5,738,865, "Controlled Release Insufflation Carrier For Medicaments", issued on April 14, 1998;
- U.S. Patent No. 5,662,933, "Controlled Release Formulation (Albuterol)", issued on September 2, 1997;
- U.S. Patent No. 5,958,456, "Controlled Release Formulation (Albuterol)", issued on September 28, 1999;
- U.S. Patent No. 6,039,980, "Sustained Release Excipient", issued on March 21, 2000;
- U.S. Patent No. 6,093,420, "Sustained Release Matrix For High Dose Insoluble Drugs", issued on July 25, 2000;
- U.S. Patent No. 6,245,355, "Sustained Release Matrix For High Dose Insoluble Drugs", issued on June 12, 2001;
- U.S. Patent No. 6,056,977, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", issued on May 2, 2000;
 - U.S. Patent No. 6,387,394, "Controlled Release Insufflation Carrier For

Medicaments", issued May 14, 2002;

- U.S. Patent Application No. 09/879,296, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", filed June 12, 2001;
- U.S. Patent Application No. 08/151,369, "Bioadhesive Tablet For Non-Systemic Use Products", filed November 12, 1993, now abandoned;
- U.S. Patent Application No. 09/676,376, "Sustained Release Matrix Systems For Highly Soluble Drugs", filed September 29, 2000;
- U.S. Patent Application No. 09/654,691, "Sustained Release Heterodisperse Hydrogel Systems For Insolube Drugs", filed September 5, 2000; and
- U.S. Patent Application No. 09/842,289, "Sustained Release Matrix For High Dose Insolube Drugs", filed April 25, 2001.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (c), before the mailing date of a final Office Action on the merits. Accordingly, a check in the amount of \$180.00 is enclosed.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

In the event any additional fee is due in connection with this response or if any fee has been overpaid, the Assistant Commissioner is hereby authorized to charge said deficiency or overpayment to our Deposit Account No. 50-0552.

Respectfully submitted,

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By:

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